

REMARKS

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and the following remarks.

Claims 1-13 are pending in the application, with Claims 1, 7, and 12 being independent. Claims 1, 7, and 12 have been amended herein. No new matter has been added.

Double Patenting Rejection

Claims 1-13 have been rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-22 of U.S. Patent No. 6,743,417 ("Glassman '417"). Without conceding the propriety of this rejection, and to expedite prosecution of the present application, Applicants herewith submit an executed Terminal Disclaimer to Obviate a Double Patenting Rejection Over a "Prior" Patent, along with an appropriate fee. A Statement Under 37 C.F.R. § 3.73(b) establishing the right to act on behalf of the assignee with regard to the application is also submitted herewith.

The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991). The filing of a terminal disclaimer serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection. *Id.*; M.P.E.P. § 804.02. Based upon filing of the Terminal Disclaimer and accompanying fee, Applicants respectfully submit that the obviousness-type double patenting rejection should be withdrawn.

Section 103(a) Rejection

Claims 1-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/19186 ("the Sun PCT") in view of U.S. Patent No. 5,661,170 ("the Chodosh patent"). This rejection is respectfully traversed.

Independent Claim 1 of the invention, as presented herein, recites a method of treating onychomycosis comprising administering to a nail area of a patient a composition that is effective for treating onychomycosis and that comprises urea as the sole active antifungal

ingredient, Vitamin E, and one or more dermatologically acceptable excipients. In the composition of Claim 1, the urea is present in an amount of from about 30 to about 50 wt-%.

Independent Claim 7 of the invention, as presented herein, recites a method of treating onychomycosis comprising administering to a nail area of a patient a composition that is effective for treating onychomycosis and that comprises urea as the sole active antifungal ingredient, an antioxidant, and one or more dermatologically acceptable excipients, wherein the urea is present in an amount of from about 30 to about 50 wt-%.

Independent Claim 12 of the invention, as presented herein, recites a method of treating onychomycosis comprising administering to a nail area of a patient a composition comprising urea as the sole active antifungal ingredient, an antioxidant, and one or more dermatologically acceptable excipients, wherein the urea is present in an amount therapeutically effective for treating onychomycosis.

The Office Action states that the Sun PCT teaches a method of treating fungal diseases of the nail comprising administering a composition comprising 1-50% urea, an antioxidant consisting of 10.0% N-acetyl-L-cysteine, and 3.0% mineral oil. As conceded in the Office Action, the Sun PCT does not disclose vitamin E; however, the Chodosh patent is cited as disclosing vitamin E. The Examiner has taken the position that it would have been obvious to combine the teachings of the Sun PCT and the Chodosh patent to arrive at a third composition that includes vitamin E.

The Sun PCT relates to the treatment of fungal diseases in nails through topical administration of a sulfhydryl-containing amino acid and urea. According to the Sun PCT, the sulfhydryl-containing amino acid and the urea are administered in an amount sufficient to enhance permeation of antifungal drugs through nail tissue, either before or preferably at the same time that topical administration of an effective amount of an antifungal drug occurs. According to the Sun PCT, urea is administered not as an antifungal agent, but as an agent that helps enhance the effect of a distinct, other antifungal agent, such as itraconazole, ketoconazole, or miconazole nitrate. The Sun PCT states that "urea's principal contribution to the efficiency of the formulation used in the invention is to inhibit the nail keratin from returning to its original densely packed cross-linked state ... so that the nail remains more permeable to the antifungal drug over a longer period of time." Therefore, the Sun PCT thus does not teach or suggest the

methods of independent Claims 1 and 7, wherein the administered composition is effective for treating onychomycosis and comprises urea as the sole active antifungal ingredient. Nor does Sun teach or suggest the method of independent Claim 12, wherein the administered composition comprises urea as the sole active antifungal ingredient, and the urea is present in an amount therapeutically effective for treating onychomycosis.

The Chodosh patent relates to antimicrobial compositions that contain an antimicrobial agent in admixture with a surfactant. The preferred antimicrobial agents are quaternary ammonium compounds, but other antimicrobial agents, such as imidazoles and triazoles, can be used instead of, or in conjunction with, the quaternary ammonium compounds. According to the Chodosh patent, the antimicrobial compositions are preferably prepared with a preservative or mixture of preservatives, in an amount generally below about 1.5 wt % of the composition. Imidazolidinyl urea and diazolidinyl urea are listed as common preservatives.

Even assuming that it were proper to combine the Sun PCT and the Chodosh patent in the manner suggested in the Office Action, Applicants submit that the proposed combination would still not teach or suggest the present claimed invention. The Chodosh patent discloses nothing about using urea as the sole active antifungal ingredient in effectively treating onychomycosis, and, as such, it does not remedy the deficiencies of the Sun PCT, noted above, with respect to the independent claims.

For at least the foregoing reasons, Applicants submit that independent Claims 1, 7, and 12 patentably distinguish the invention over the cited art, whether taken alone or in combination. Reconsideration and withdrawal of the § 103 rejection are respectfully requested.

Further, Applicants submit that all of the dependent claims are also patentable, at least by reason of their dependency from the independent claims.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action, and, as such, the present application is in condition for allowance. If the Examiner

believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,

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